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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,322	03/29/2004	Christina Kabbash	45775-Z/JPW/AJM/DNS	5097

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,322

Applicant(s)

KABBASH ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/10/05; 4/4/05; 3/29/04; & 3/1/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 60-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 60 and 65-82 is/are rejected.
- 7) ☒ Claim(s) 61-64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/10/05; 4/4/05; & 3/29/04

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the following: (1) the preliminary amendment filed 3/29/04 wherein the specification was amended; claims 27-40, 58, and 59 were canceled; and claims 1, 13, 41, and 48 were amended. (2) The amendment filed 3/1/05 wherein claims 1 and 2 were amended; claims 13-59 were canceled; and claims 60-82 were added.

Note: Claims 1-12 and 60-82 are pending.

APPLICANT'S INVENTIONS

2. The instant invention is directed to a method of inhibiting growth of a bacterium, a method of alleviated the symptoms of a bacterial infection, a method of altering the pathway of fatty acid synthesis in a bacterium, and a method of determining whether or not a bacterium is sensitive to gemfibrozil as set forth in independent claims 1, 60, 67, 76, and 78.

APPLICANT'S ELECTION

3. Applicant's election with traverse of Group I is acknowledged. The traversal is on the ground that newly added claims 60-82 read on elected Group I. Applicant's argument is found persuasive. Thus, Group I has been modified to include claims 60-

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82. Furthermore, it is noted that the restriction is deemed proper and is therefore made FINAL.

112 FIRST PARAGRAPH REJECTIONS (New Matter)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The incorporation of '(or CH₂)' into the structure (claim 1, line 4) is not consistent with the disclosure. Applicant is respectfully requested to point to page and line number wherein support can be found for the amendment to the claim.

In addition, the replacement of 'C=C-C₂HOH' with 'C≡C-CHOH' is not consistent with the specification. Furthermore, it is unclear why a double bond was replaced with a triple bond. Applicant is respectfully requested to point to page and line number wherein support can be found for the claim as amended.

112 SECOND PARAGRAPH REJECTIONS

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-12 and 67-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12 and 67-82: The claims as written are ambiguous because the variable X (see claim 1, lines 7, 14, and 15) is defined as an integer from 1-10 (see claim 1, lines 22-23) instead of a substituent as required in claim 1 lines 7, 14, and 15.

Claim 1, lines 11-12: The claim as written is ambiguous because of the phrase 'wherein a linkage...-C-;' is unclear because the structure discloses specific linkages (O or CH₂) to the benzene ring. However, the phrase discloses that the linkage is nitrogen, sulfur, oxygen, or carbon.

Claim 1, line 5: The term 'comprises' is not acceptable Markush terminology. Applicant is respectfully requested to replace the term with acceptable terminology (see MPEP 803.02).

Claim 1, line 13: The phrase 'may be' is not acceptable Markush terminology. Applicant is respectfully requested to replace 'may be' with 'is selected from'.

Claim 1, line 22-23: Applicant refers to the variable 'n'. However, the variable 'n' is not present in the claims.

Claim 1, lines 22-23: Applicant is reminded that 'may' is not acceptable Markush terminology. Applicant is respectfully requested to replace the phrase 'may independently be' with 'is independently'.

Claim 1, lines 23-24: The term 'comprises' is not acceptable Markush terminology.

Claim 2, line 1: The term 'comprises' is not acceptable Markush terminology.

Claim 3, line 4: 'A = CH₂' is confusing because Applicant does not allow the variable A to be CH₂ in its definition.

Claim 4, line 4: The phrase 'Q = 0' is ambiguous because in claim 1, lines 22-23, Q is defined as an integer from 1 to 10.

Claim 5: The claim as written is confusing because it is unclear what is the definition of R₃. In addition, it is unclear if Applicant intended line 3 (R₁ = ...-OH) to be on a single line. Furthermore, the claim is ambiguous because the variable Q cannot be zero.

Claim 6, line 5: The claim is ambiguous because the variable Q cannot be zero.

Claims 67-75: The claims as written are ambiguous because it is unclear what symptoms are being alleviated. It is noted that the specification, see page 3 of PG-Pub. [0045] – [0047], is directed to the embodiment dealing with alleviating the symptoms of bacterial infection. However, no symptoms are disclosed which may be alleviated.

Claims 76 and 77: The claims as written are ambiguous because it is unclear which pathway(s) Applicant is claiming may be altered using gemfibrozil. On page 4, paragraphs [0053] – [0056], the embodiment dealing with the pathway of fatty acid

synthesis is disclosed. However, no particular pathways are disclosed which are applicable to the instant invention are disclosed.

Claims 78-82: The claims as written are ambiguous because the term 'sensitive' is a relative term. Thus, since Applicant has not set forth a definition of what the term means as it relates to the instant invention, one cannot ascertain what is being claimed.

102 REJECTIONS

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 78, 79, 81, and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Yajko et al (Abstracts of Interscience Conference on Antimicrobial Agents and Chemotherapy, 1995, A105).

Yajko et al disclose a study wherein gemfibrozil enhanced the intracellular activity of ciprofloxacin. *Mycobacterium avium* complex was used to test the gemfibrozil-ciprofloxacin composition. The concentration of gemfibrozil used in the study was 20 µg/ml (see the entire document, A105). Thus, Yajko et al disclose that bacterium is sensitive to gemfibrozil because intracellular activity is enhanced. Hence, both Applicant and Yajko et al disclose that bacterium is sensitive to gemfibrozil.

10. Claims 1, 2, 4, 6, and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al (Journal of Bacteriology, May 1966, Vol. 91, pages 1854-1858).

Smith et al disclose the growth inhibition of mycoplasma. In particular, Smith et al disclose the used of para-chlorophenoxy isobutyric acid as one of the inhibitors used in their study (see entire document, especially abstract; and page 1855, Table 1). In particular, para-chlorophenoxy isobutyric acid is encompasses in Applicant structure when R1-R6 = hydrogen and (A)Q = absent. Thus, both Applicant and Smith et al disclose growth inhibition of a bacterium as set forth in independent claim 1.

Note: It is noted that in independent claim 1, Applicant does not define the variable Q as zero. However, in claim 4, for example the variable Q is defined as zero. Thus, the rejection is being made on the basis that the variable Q is 0-10.

11. Claims 1, 2, 11, 12, 60, 65, 66, 78, 79, 81, and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Rudin et al (J. Exp. Med., 1992., Vol. 176, pages 1439-1447).

~~Rudin et al~~ disclose that gemfibrozil enhances the Listeriacidal effects of fluoroquinolone in J774 macrophages (see entire document, especially, abstract; [age 1442, left column, first complete paragraph; page 1444, Table 1; and page 1445, Table 2). The concentration of gemfibrozil ranged from 0.2 to 0.5 millimolar (page 1440, left column, first incomplete paragraph). Thus, both Applicant and Rudin et al disclose bacterium that is sensitive to gemfibrozil. In addition, since the cytotoxic effect of the

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bacteria on the cells is reduced with NFX (norfloxacin) in combination with gemfibrozil, a skilled practitioner in the art would recognize that growth of the bacterium.

ABSTRACT

12. The abstract of the disclosure is objected to because the abstract is too long.

Correction is required. See MPEP § 608.01(b).

CLAIM OBJECTIONS

13. Claims 61-64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


COMMENTS/NOTES

14. While no prior art has been cited against claims 61-64, it should be noted that the invention has been examined to the extent possible in light of the 112 rejections disclosed above. Thus, the limitations present in combination with the appropriate intervening claim are distinguished over the art because the additional limitations are not disclosed/suggested by the prior art of record.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1616

May 10, 2005
